ISO 9000:2015
How to write procedure?

* Success in the implementation of ISO 9000 basically depends on how each of its individual procedure is decisively written.

* Procedures provide a standardized reference or guide for employees to perform excellently assigned tasks.

* Reference where they will provide guidance and consistency when employees perform quality related tasks.

Procedure should specify

1. What should be done?
2. Who will do it?
3. When will it be done and in what sequence?
4. How will it be done?
5. What equipment, tools or materials will be used?
6. What forms or other documents will be used.?
7. An appendix for all forms used in the procedure
8. A flow chart for the procedure (where applicable the flow chart can be the procedure if it is understandable)
9. Signed, dated authorizations under revision control with controlled distributions.

Other considerations to incorporate:

* Definitions
* Referencing standards
* Documentation
* Quality Records

The Bottom Line

For ISO 9001 compliance, the bottom line is to write what you do, then do what you have written.

Tips on procedures

* **Tip 1:** The more general the procedure, the more flexible, however, the more specific the guidance, for those responsible for carrying out job duties, the easier the system is to maintain.

* **Tip 2:** There must be at least one procedure for each element for the standard, depending upon complexity of the element.

* **Tip 3:** A reference can be put into the procedures referencing other procedures if you are documenting the elements other than by the ISO Standard numbering scheme.

* **Tip 4:** Try to keep the procedures from being to specific. Assign who (by job title) does a task and when does it happen.

* **Tip 5:** There must be consistency in action.

* **Tip 6:** Use of a flow chart is not required, however, is highly recommended.

Writing format

* Present your content in a **logical** and **easy-to-read** sequence that makes sense to the targeted audience.
* Present enough information about your content that helps the audience understand the importance of your procedure topic.
* A writing format contains a specific number of section headings and never changes after the writing format is approved for use

* 1.0 Purpose
* 2.0 Scope
* 3.0 Definitions
* 4.0 Responsibilities
* 5.0 Procedures
* 6.0 Revision History

1.0 Purpose

* Contains introductory paragraph about the objectives and reasons for writing the document
* Maximum of three (3) sentences
* Can begin with, "This procedure contains guidelines for …"

* **Be careful:**
  * Don't use cryptic words or acronyms that immediately confuses the reader
  * Don't use subheadings or bullets
  * Don't use fragmented sentences

2.0 Scope

* Lists the audience or targeted users or customers
* Scope can also include an exclusion statement like, “does not include accounting personnel”
* Can be a fragmented sentence

* **Be careful:**
  * Don’t state, “All employees” when the document actually targets two or more areas

4.0 Responsibilities

* Summary of roles and responsibilities of the individuals or groups that perform actions in a policy or procedure
* The "Responsibilities" section often parallels the flow of the "Procedures" section, where applicable
* The responsibility section typically has at least two sentences:
  * "The [Title of Highest Approver] shall ensure compliance to this procedure"
  * "Employees are required to…"

* **Be Careful:**
  * There must be a "compliance" statement in every policy or procedure document
  * Don't write procedural statements in this section; rather keep to the responsibilities of the roles stated
  * Don't write actual names of persons; instead state only their roles or functions

RASCI matrix

Welcome | RASCI Matrix

RASCI Matrix

Task Name	Responsible	Accountable	Supported	Consulted	Informed
Event					
T1	Bob	Tom	Tim, Mary	Joe	Sue
T2	Mary	Tom	Joe, Sue	Jim	Bob
T3	Jim	Sue	Mary, Bob	Tom	Tim
T4	Bob	Tom	Sue	Tim	Mary
T5	Tom	Mary	Joe	Bob	Sue, Mary
T6	Jim	Tom	Tim, Sue, Bob		Mary
T7	Jim	Tom	Joe		

	Participant 1	Participant 2	Participant 3
Activity 1			
Activity 2			
Activity 3			

R - Responsible
P – Participate
I – Informed

5.0 Procedures

* The **Procedures section heading** describes the activities and personnel necessary to carry out the intent of the procedure

* The **Procedures section heading** is required

6.0 Revision History

* Contains the history of the document from the first release to the most current.
* The first release can be shown with a letter “A” or “1” in the “Revision Letter” field in the header information within the Writing Format
* Complete descriptions can be written in table form or referenced in an attachment

* **Be careful:**
  * Most readers don’t care about this section so don’t spend too much time on the completion of this section heading
  * Don’t omit descriptions of revisions when changes occur
  * Don’t forget to increment the revision letter or number when revisions occur

Flowchart

Figure 1: FLOWCHARTING SYMBOLS AND USE

Activity or Task	Depict time consuming steps in a process. *Examples: Inspect a product, machine a part, etc.*
Decision	Depict questions/checks and show alternative outcomes depending on the result. *Examples: Is the part nonconforming?* *If **yes**, do one thing. If **no**, do another.*
Document or record (used or generated)	Depict documents used to perform tasks or records generated by the activity. *Examples: Work Instructions (in)* *Scrap Record (out)*
Terminator (Start or End)	Depict the start or end of a procedure or work instruction.
Flow	Depict the flow of logic, decisions, or steps of documentation.
A	Depict transfer of flow to a location or show the identity of a location.

The End